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Regulatory Directive DIR2017-03

# Registration of Pesticides for Emergency Use: Revised Procedures

*(publié aussi en français)*

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The purpose of this document is to inform registrants, user groups, government agencies and other interested stakeholders about the procedure for registering pesticides or amending registrations for emergency control of pest infestations where currently registered pesticides and non-chemical control methods or practices are insufficient to address the pest outbreak.

This regulatory directive replaces Regulatory Directive DIR2001-05, *Registration of Pesticides for Emergency Use*, dated 17 August 2001.

## 1.0 Introduction

Under section 18 of the Pest Control Products Regulations, the Minister of Health may register a pest control product or amend the registration of a pest control product to permit its use, for a period not exceeding one year, for the emergency control of seriously detrimental pest infestations. In addition, under paragraph 18(1)(a), an emergency registration may not be extended beyond one year.

The process outlined in this document addresses emergency pest situations only. Emergency registrations are not a tool for early or extended access to pest control products (pesticides) not currently registered for that use. For known or ongoing pest problems where no registered product is available, applicants will be referred to the normal registration processes in place to address such situations.

An emergency is generally deemed to exist when both of the following criteria are met:

A. An unexpected and unmanageable pest outbreak or pest situation occurs that can cause significant health, environmental or economic problems; and

B. Registered pesticides and cultural control methods or practices are insufficient to address the pest outbreak.

Examples of emergency pest situations may include, but are not limited to, invasion by a new pest organism, a sudden and significant increase in pest pressures due to environmental or other conditions, or the need for an alternative application method due to adverse weather conditions.

When an emergency pest situation persists beyond the expiry date of the original emergency registration, the applicant may make a new emergency use application for the same pest. However, the application package should be accompanied by a pre-submission application request from the product registrant for the full registration of that use. The use should also be prioritized within the sponsor province to demonstrate the need for the registration. Any subsequent applications for an emergency use for the same pest situation must be accompanied by a new, updated data package, including justification for the continued need for the emergency use, and considering any newly registered alternatives that may address the pest situation.

As a condition of the emergency request, the Pest Management Regulatory Agency (PMRA) may impose special terms and / or conditions on the emergency use, such as additional precautionary label statements, personal protective equipment, specific application equipment or engineering controls, or the requirement for additional studies or post-use monitoring activities.

Because emergency registrations require and receive immediate attention, consideration will be given first to products that are registered in Canada where the risks to human health and the environment have been assessed previously for the product. When no Canadian-registered product is available, consideration may be given to products registered in other jurisdictions, provided the active ingredient is registered in Canada. The emergency use will be considered only if there is evidence that the health and environmental risks are acceptable and the product has value in addressing the emergency pest situation.

## 2.0 Sponsorship

Emergency registrations are sponsored by the provincial ministry or federal agency that supports the management of the pest problem (for example, the provincial Ministry of Agriculture). The sponsor is responsible for compiling all information and rationales as well as the required letters of support or no-objection from each province participating in the emergency use application before submitting them to the PMRA in one application package. The onus is on the sponsor to ensure that there is discussion with the ministry responsible for pesticide regulation (such as the Ministry of the Environment) in each province involved, and that any issues related to the emergency use of the proposed pesticide are resolved at the provincial level before the application package is submitted to the PMRA.

## 3.0 Application Process

All information pertaining to the emergency registration application must be compiled by the sponsor and submitted to the PMRA using the Electronic Pesticide Regulatory System (e-PRS) Secure Web Portal, or sending the PMRA Regulatory Zip (PRZ) file to pmra-arla.docs@hc-sc.gc.ca. Information regarding this process can be found on the Pesticides and Pest Management section of the Canada.ca website (*https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/registrants-applicants/electronic-pesticide-regulatory-system.html*).

The sponsor should ensure that the compiled package is complete, including all letters of support or no-objection, including those from the provincial ministry responsible for pesticide regulation, before submitting it to the PMRA, since the review process cannot be completed until all supporting information has been received. A checklist of the information required for an emergency registration application can be found in Appendix I.

## 4.0 Submission Organization

The following subsections will outline the information required for an emergency registration application. In addition to the administrative requirements (letters, forms and labels), all technical information, including the supporting health, environmental and value information, should be in MS Word format and organized under the headings listed under Subsections 4.1 to 4.4.

### 4.1 Administrative and Regulatory Requirements

A cover letter, letters of support or no-objection, required forms, the processing fee, and draft supplemental labels should be submitted with the emergency registration application. Specific information on these requirements can be found in Appendix II.

### 4.2 Health and Environmental Information

The PMRA will use all available relevant information in its possession to support the health and environmental assessments. In addition, information may be required under the Health and Environmental Information section of the application as specified below.

**Human activities associated with the emergency use of the product**

Additional information specific to the emergency registration application may be required regarding mixer/loader/applicator and/or postapplication activities.[1]

**Residue Data**

For emergency registration requests in which a food or feed use is proposed, relevant residue data (either in PMRA's possession or provided by the applicant), must demonstrate the level of residues anticipated in the crops when treated according to the proposed use pattern.

During the review of an emergency registration, the Agency will determine a residue limit that is specific for the pesticide-commodity combination use within the context of the emergency registration. The PMRA will notify the relevant stakeholders, accordingly.

**Environment**

Additional information on environmental exposure specific to the emergency registration request may be required.

### 4.3 Value Information

The following information should be provided under the Value Information section of the application.

**Description of emergency situation**

In the dossier of information supporting the application, a description of the nature and scope of the pest problem, including geographical distribution of the pest infestation, should be provided.

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[1] For additional information, refer to Guidance for Developing Datasets for Conventional Pest Control Product Applications (DACO Part 5.2) https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/policies-guidelines/guidance-developing-applications-data-codes-parts-1-2-3-4-5-6-7-10.html

**Rationale for emergency use**

The sponsor must describe how the application meets both criteria for an emergency use described in Section 1.0. It must include a rationale addressing why the pest outbreak is considered to be a seriously detrimental infestation with respect to health or the environment, or why it would result in significant economic loss. The rationale should also address why the pest was not considered to be a problem in recent years, and why the situation cannot be addressed either with the currently registered alternatives, or through registration via the normal regulatory process. The sponsor should also justify why the emergency use is required for the requested time period.

**Description of proposed product and use pattern**

A summary of the proposed product and use pattern should be provided, including: the common, trade and chemical (International Union of Pure and Applied Chemistry) names for pesticide(s) proposed, the *Pest Control Products Act* registration number(s), the application rate (of both the product and active ingredient), maximum number of applications per use season or crop cycle, number of crop cycles per year (if applicable), initial application timing, application intervals, application method, re-entry interval, and pre-harvest interval (if for crop use). The applicant is encouraged to provide this information in table format. If the proposed product is approved for the same use in another country, the registration number in the country in which the product is registered, and a copy of the label of the approved product should also be provided.

**Registered alternatives and cultural control methods**

Applicants should provide the product names, registration numbers, and indicate the type of control measure (for example, conventional or non-conventional pesticide, pheromone, or cultural control method) for each alternative end-use product and an explanation for why these are not acceptable to manage the pest outbreak. The applicant is encouraged to provide this information in table format.

**Explanation for choice of product and proposed use pattern**

The applicant should describe what level of pest management is required to mitigate the outbreak, and provide evidence that the product will deliver an acceptable level of pest control when applied as proposed. Applicants can provide efficacy data (including foreign data), use history, scientific rationales or other scientific information to address product performance, resistance management and crop tolerance (where applicable). If resistance to other registered alternatives is cited as justification for the emergency use, evidence supporting this should be submitted.

**Description of socio-economic impact**

Applicants should discuss the anticipated economic, social, and environmental costs that may occur without the emergency registration. For agricultural emergency uses, a description of crop value can be included, as well as the expected percent field loss or percent economic loss of gross or net revenues without the emergency registration. For non-agricultural emergency uses,

the impact of not accessing a pest control product can be described, including the potential ecological loss or any adverse effects on the environment or human health.

### 4.4 Other information

Other information related to the emergency use may be requested during the assessment period, including information such as if the product has to be imported for use, and the need for Canadian labels prior to distribution and use within Canada. Products being imported into Canada should be accompanied by the Canadian emergency label.

Emergency registrations may require additional supporting information or action under other legislation such as the *Food and Drugs Act* and *Regulations*, or the *Fisheries Act*. The granting of an emergency registration allows a product to be imported, distributed and used under the *Pest Control Products Act*, but it is up to the registrant or sponsor, as the case may be, to ensure that any other applicable legislation has been satisfied.

## 5.0 Emergency Registration in Subsequent Years

An emergency registration cannot be granted for longer than one year, and may not be renewed. Where the pest infestation is predicted to remain an ongoing issue in future years, the PMRA expects the sponsor and registrant to prioritize the pest issue, and pursue full registration of the use through normal regulatory processes as soon as possible. If the pest situation persists beyond the initial emergency registration period, a new emergency registration application that includes all documentation listed above must be submitted for review. Recent information is required demonstrating that the pest outbreak still meets the criteria for an emergency registration, what progress has been made to register the use through normal regulatory channels, and when the application package for full registration will be submitted to the PMRA. The application should also be accompanied by a pre-submission request from the product registrant for the full registration of that use. If the new emergency application no longer meets the criteria of an emergency pest situation, or insufficient progress has been made towards full registration, then the application will be denied.

# Appendix I

## Table 1 Checklist of the information required for an emergency registration application.

| 1.0 Administrative Requirement (refer to Section 4.1) | ☑ |
|---|---|
| Cover letter from sponsor | |
| Letter of registrant support | |
| Letter of provincial / territorial support from the department[2] responsible for pesticide use (for example, Ministry of Agriculture, Ministry of Health) signed by FPT member or a higher level of authority for each participating province or territory. | |
| Letter of provincial / territorial support or no-objection from the department responsible for pesticide regulation (e.g., Ministry of Environment) signed by FPT member or a higher level of authority for each participating province or territory. | |
| Application form (PMRA/ARLA 6005) | |
| Proposed New Uses form (PMRA/ARLA 6023) | |
| Fee Form (PMRA/ARLA 6011) and fees[3] | |
| Statement of Product Specification Form (PMRA/ARLA 6003); applicable only for end-use products not currently registered in Canada | |
| Draft English emergency use label in MS word format | |
| Draft French emergency use label in MS word format | |
| | |
| **2.0 Technical Information (refer to Sections 4.2 to 4.5):** ***Please note that all technical information (Value, Health, Environmental, Other) must be provided in MS Word.*** | ☑ |
| | |
| **Health and Environmental Information** | |
| Human activities associated with emergency use of the product | |
| Crop Field Trial Residue Data (if applicable) | |
| Relevant Environmental Information | |
| | |
| **Value Information** | |
| Description of emergency situation. | |
| Rationale for emergency use. | |
| Description of proposed product and use pattern. | |
| Summary of registered alternatives (table format). | |
| Explanation for choice of product and use pattern. | |
| Description of socio-economic impact. | |
| | |
| **Other Information** | |
| Requirements for product importation or re-labelling | |
| Information on progress towards full registration of the use through normal regulatory channels[4] | |

2 For provinces or territories with more than one department responsible for pesticide use, a letter of support from each department is required. See Appendix II

3 If paying by cheque, make it payable to the Receiver General of Canada.

4 Required for any request for the same emergency use in subsequent years.

# Appendix II

## 2.0 Letters

With each application, a cover letter, a letter of support from the registrant, and letters of provincial or territorial support or no-objection are required. Letters of support from grower's groups or associations may also be included as additional supporting information.

- The cover letter from the sponsor should explain the purpose of the application. The letter from the registrant should indicate support for the proposed emergency use of their product and confirm that there is sufficient product available to address the emergency situation for the period of time required. Please note that any issues between the sponsor and the registrant regarding liability of use (for example, efficacy and/or crop tolerance) should be resolved prior to submitting an application for emergency registration.

- A letter of support or no-objection must be provided from the provincial department or agency responsible for pesticide use (for example, Ministry of Agriculture). **The letter** must be signed by the sitting member of the Federal, Provincial and Territorial Committee on Pest Management and Pesticides at a minimum. Letters from these departments or agencies must be provided from each province or territory listed on the emergency use application.

- A letter of support or no-objection must also be provided from the provincial department or agency responsible for pesticide regulation (for example, Ministry of Environment). **The letter** must be signed by the sitting member of the Federal, Provincial and Territorial Committee (FPT) on Pest Management and Pesticides at a minimum. Depending on the nature of the emergency, letters of support or no objection may involve more than one department and/or require written approval by an authority above the FPT level. Letters from these departments or agencies must be provided from each province or territory listed on the emergency use application.

## 2.1 Forms

The following forms are required:

- Application for New or Amended Registration form (PMRA/ARLA 6005),
- Proposed New Uses form (PMRA/ARLA 6023),
- Fee form (PMRA/ARLA 6011), along with payment,
- A Statement of Product Specification form (PMRA/ARLA 6003) is also required for the proposed use of any end-use product not currently registered in Canada.

### 2.2 Fees

Fees are normally provided by the sponsor but may be provided by a grower association or other stakeholders. The processing fee applies to all emergency registration applications. Refer to the Processing Fee at the following link for current fees (http://www.gazette.gc.ca/rp-pr/p2/2017/2017-02-22/html/sor-dors9-eng.php).

### 2.3 Labels

Draft emergency use labels in both English and French, in MS Word format, must be obtained from the registrant and submitted. Only information directly related to the emergency use should be included on the emergency use labels, and reference to all other uses should be deleted. The labels must clearly indicate the proposed directions for use, precautions, restrictions and all other label requirements related to the emergency use request.

The front panel of the labels must state that it is "For 'Emergency Use Only', indicate the nature of the emergency use (list the pest and host or use site), list the proposed province(s), and indicate the proposed end date of use (which is not to exceed a one year period from the date the emergency registration was granted).

Example: "**FOR EMERGENCY USE ONLY**. For sale and use only in British Columbia to suppress cottonball rot on cranberry, until 30 September 2016."